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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,674	02/23/2004	Stephen T. Kuehn	S16.12-0135	1936
27367	7590	03/18/2008	EXAMINER	
WESTMAN CHAMPLIN & KELLY, P.A.			WOO, JULIAN W	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/784,674	KUEHN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 January 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 21,28 and 36-53 is/are pending in the application.

4a) Of the above claim(s) 28,41,42 and 45-50 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 21,36-40,43,44 and 51-53 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21, 36-40, 43, 44, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 21, the grasper is said to secure at least one leaflet, which is an unpatentable part of the human body that is essentially claimed to be a structural part of the invention. The Examiner suggests language, where the grasper is said to be --configured to— or –adapted to frictionally secure at least one leaflet--.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 21, 37, and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilk (5,395,367). Under 35 U.S.C. 102(b), Wilk discloses, at least in figures 5 and 7 and in col. 8, lines 48-55 and col. 9, line 44 to col. 10, line 55; a device including a catheter (32), a gripper (35), and a leaflet fastener applicator (36a or one of “staplers” and “suture applicators”), where the fastener applicator and the gripper extend from separate shafts (35, 36) that extend simultaneously through the catheter, where the gripper extends through a first catheter (unlabeled sleeve of 35) and the fastener applicator extends through a second catheter (unlabeled sleeve of 36), where the gripper includes at least one grasper (hook 35a) that angularly moves relative to a shaft (see col. 10, lines 15-27), and where the grasper is inherently capable of frictionally securing at least one leaflet in a secure position between the grasper and the shaft (i.e., the surface of at least the hook inherently possesses friction).

Under 35 U.S.C. 103(a), Wilk discloses the invention substantially as claimed, but arguably, does not specifically disclose or illustrate in fig. 7, a gripper including a grasper capable of frictionally securing at least one leaflet in a secure position between the grasper and the shaft. Nevertheless, Wilk discloses, in col. 10, lines 31-35; that various grippers, each including an active grasper (active as compared to a hook), may be chosen and may be applied with and angularly movable with respect to the shaft; e.g., biopsy forceps, graspers, staplers, and clamps. These grippers with graspers also inherently possess friction on surfaces that may contact and secure tissue. Thus, it

would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a gripper (e.g., Wilk's forceps or grasper) for the securing of at least one leaflet, since it has been held to be within the general skill of a worker in the art to select a gripper on the basis of its suitability for the intended use as a matter of obvious design choice.

5. Claims 36, 43, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Harrison et al. (5,306,326). Wilk discloses the invention substantially as claimed. Wilk discloses a device including a catheter, a gripper having at least one grasper that move angularly relative to a shaft, and a leaflet fastener applicator (36a) with two opposing jaws passing through the catheter, such that an actuating element (36c) projecting from the proximal end of the catheter (32). However, Wilk does not disclose that the catheter has suitable dimensions for insertion into a heart and that a fastener projects from the distal end of the catheter, or that one of the jaws has a site for holding a tack and a second jaw has a site for holding a cap.

With respect to the catheter dimensions: It would have been a matter of obvious design choice to size the catheter as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to the fastener projecting from the distal end of the catheter or jaws respectively holding a tack and a cap: Harrison et al. teach, at least in figures 8A-9 and in col. 7, line 24 to col. 8, line 30; a device including a fastener (staple 54 or tack 90)

projecting from the distal end (at 68 or 66) of a catheter (80), and that one of the jaws (66) has a site for holding a tack (90) and a second jaw (66) has a site for holding a cap (96). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison et al., to include a fastener projecting from the distal end of the catheter, or a jaws having a site for holding a tack and a second jaw having a site for holding a cap, in the device of Wilk. Such modifications would allow the device to laparoscopically fasten tissues or repair wounds within a patient's abdominal wall or internal organ.

6. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Hathaway et al. (5,304,184). Wilk discloses the invention substantially as claimed. Wilk discloses a device including a gripper, where the gripper may be one of several instruments (e.g., "hook," "biopsy forceps," "suction devices," "staplers, suture applicators and clamps"). However, Wilk does not disclose that the gripper includes a grasper and a plunger, where the plunger can be moved along one of the separate shafts toward the grasper, and where the plunger comprises arms to push the leaflets towards the grasper. Hathaway et al. teach, at least in figures 17a-17d and in col. 10, line 56 to col. 11, line 4; a gripper that is a laparoscopic suture applicator including a grasper (53) and a plunger (62) with arms (57) that can push tissue towards the grasper. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply the gripper of Hathaway et al. with Wilk's device. Such a device would allow a laparoscopic, suture-based method of tissue wound closure without the need for other devices or therapeutic materials and

without the necessity of direct visualization of a tissue opening, which is to be closed by the suture applicator.

7. Claim 44 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of Harrison et al. as applied to claim 43 above, and further in view of Bolanos et al. (5,423,858). Wilk in view of Harrison et al. discloses the invention substantially as claimed. Wilk in view of Harrison et al. discloses a device with opposing jaws respectively holding a tack and a cap. However, the combination does not disclose a slot in the jaw for holding a tack, where the tack is slidably positioned within the slot. Bolanos et al. teach, at least in figures 4 and 6 and in col. 5, lines 3-20; a device including jaws having slots (60) for respectively holding a tack (120) and a cap (130), where a tack can be slidably positioned (i.e., centered) within the slot. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bolanos et al., to modify the jaws of the device of Wilk in view of Harrison et al., such that they have slots for positioning and holding a tack. Such a slot would accommodate and engage the head (92) of tack 90 and would allow positioning of and improved mechanical support for the tack as it held by the jaw and as it is driven into tissue.

8. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over over Wilk (5,395,367) in view of Harrison et al. (5,306,326), and further in view of Kortenbach (6,086,600). Wilk in view of Harrison et al. discloses the invention substantially as claimed, but does not disclose that the first jaw comprises a track where the tack can be slidably positioned along the track. Kortenbach teaches, at least in

figures 30 and 43, teach a device jaw including a track (224 or 324), where a tack (227a or 327a) is slidably positioned opposite a site for holding a cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kortenbach, to modify the first jaw of Wilk in view of Harrison et al., so that it includes a track. Such a track would not allow convenient, slidable loading and positioning of a tack in a jaw, the track would allow secure holding of the tack while it is inserted into and applied in a patient's body.

***Response to Amendment***

9. Applicant's arguments filed on January 18, 2008 have been fully considered but they are not fully persuasive: See the new and restated grounds of rejection above. That is, Wilk indeed discloses or teaches a gripper having at least one grasper that moves angularly relative to the shaft, where the grasper is capable of frictionally securing at least one leaflet in a secure position between the grasper and the shaft. The gripper and the fastener applicator of Wilk are each angularly movable with respect to a shaft, even though figure 7 shows element 35a aligned with the longitudinal axis of shaft 35. Wilk's figure 7 is provided to exemplify three tools usable with a catheter, where the tool tips are oriented as shown for purposes of illustration.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Danzig (4,924,864) teaches a device a fastener applicator.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

March 13, 2008